

Rejection under 35 U.S.C. § 103(a)

Claims 19-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson. Independent claim 19 recites, in part, a seal comprising a bladder filled with a molded material in a predetermined configuration having a durometer value less than about ten on a Shore OOO scale.

Briefly, Johnson discloses a diver's face mask having a rigid transparent frontal portion and rigid transparent peripheral portions. See Johnson, col. 1, lines 51-52. The mask includes sealing means (20), which is designed to accommodate differing facial features by including a suitably shaped layer of pliable neoprene (21) wrapped around and bonded onto a length of resilient surgical rubber tubing (22). See Johnson, col. 2, lines 42-45 and Figure 2A (emphasis added).

Applicants thank the Examiner for clarifying his interpretation of the Johnson reference. Specifically, the Office Action explains, on page 3, that "the examiner does not contend that it would have been obvious to fill tube 22," and states, on pages 3-4, that "tube 22 is the fill material" and that "it would have been obvious to have formed tube 22 out of a material having the claimed hardness as simply a matter of design choice, noting the lack of criticality of this hardness in the applicant's [sic] specification."

Applicants respectfully traverse this rejection for at least the following reasons. First, Johnson's rubber tube is not and does not suggest or motivate an ordinarily skilled person to arrive at "a molded material in a predetermined configuration," as recited in claim 19. Second, Johnson does not provide the requisite suggestion or motivation to modify the hardness of Johnson's hollow rubber tube to arrive at the invention recited in claim 19. Furthermore, the knowledge of one skilled in the art not only does not supply this requisite suggestion or motivation, but it actually teaches away from modifying Johnson to obtain the seal recited in claim 19.

First, Johnson does not teach, suggest, or motivate "a molded material in a predetermined configuration" recited in claim 19, because it is believed that Johnson's resilient surgical rubber tubing 22 is an extruded rather a molded article. Specifically, as understood by skilled artisans, manufacturing processes for polymer products include different types of molding (for example,

hot-compression, injection, transfer, and cold molding), casting, and extrusion. See E. Paul DeGarmo, Materials and Processes in Manufacturing, pg. 219 (5th ed. 1979) (Tab A). Unlike molding, extrusion is defined in the art as “[a] process in which a hot or cold semisoft solid material, such as metal or plastic, is forced through the orifice of a die to produce a continuously formed piece in the shape of the desired product” (see McGraw-Hill Dictionary of Scientific and Technical Terms, pg. 725 (5th ed. 1994) (Tab B)), and such a process is used to produce plastic products with long, uniform cross-sections. See DeGarmo at 223 (Tab C). In contrast, as understood in the art, molding involves “introducing liquid, granular, or powdered material into a previously prepared mold cavity.” DeGarmo at 9 (emphasis added) (Tab D). Applicants respectfully submit that it is believed that Johnson’s rubber tubing (that clearly has a long uniform cross-section) is a plastic product that is manufactured by extrusion, rather than by molding. Thus, because Johnson does not teach or suggest “a molded material in a predetermined configuration” recited in claim 19, Applicants submit that independent claim 19, as well as claims 20-29 dependent therefrom, is novel and non-obvious over Johnson, and respectfully request withdrawal of the rejection.

Further, Applicants respectfully submit that neither Johnson, either alone or in combination with the knowledge of one of ordinary skill in the art, suggest or motivate modifying the hardness of Johnson’s resilient surgical rubber tubing to obtain the seal recited in claim 19.

As a preliminary matter, Applicants respectfully reiterate that, contrary to the statement on page 3 of the Office Action, Applicants do teach the benefits of the very soft seal recited in claim 19. On page 3, lines 19-21, the application specification highlights a need to overcome the limitations of known designs, by providing an improved nasal mask that provides a consistent, reliable nasal area seal, while being comfortable to wear. See Specification, page 2, lines 1-6. Both the softness of a gel seal according to the invention and the configuration of devices according to the invention which invite minimal contact between the user's epidermal areas and the device, combine to create this comfortable and reliable seal about the user's nares. See Specification, page 3, lines 5-8. See also, Specification, page 7, lines 15-21. Furthermore, care is taken in the specification to describe a manner in which one can determine the durometer of

the seal fill material, because this material is too soft for measurement by ASTM-approved Shore durometer test methods. See Specification, page 14, line 13 to page 15, line 27.

Applicants respectfully submit that there is no motivation to modify Johnson in order to arrive at the invention recited in claim 19. It is well settled that, to modify a reference, there must be some suggestion or motivation to do so in the reference itself or in the knowledge generally available to one of ordinary skill in the art that lies outside the disclosure of the patent application. See, e.g., MPEP §2142 (8th Ed., August 2001). Absent this motivation, a rejection under 35 U.S.C. § 103(a) should not be maintained.

Neither Johnson nor the knowledge of one of ordinary skill in the art provides the requisite suggestion or motivation to modify the hardness of Johnson's rubber tubing to arrive at the invention recited in claim 19. Specifically, Applicants submit that Johnson does not teach the specific hardness of the rubber tubing or teach or suggest using any material other than resilient surgical rubber. This is not surprising, because the teachings and objectives of Johnson are divergent from Applicants'.

In particular, Johnson identifies surgical rubber tubing (also known in the art as "latex rubber tubing" or "latex surgical tubing") as a particular material for its seal. Although Johnson is silent with respect to any specific hardness value or range of hardness values of its resilient surgical rubber tubing, as understood by skilled artisans, durometer hardness of such rubber material generally ranges from 27 to 53 on a Shore A scale, i.e., substantially higher than that recited in claim 19. See, e.g., Dipped Hytone® Natural Rubber Latex Tubing Typical Properties, Hygenic Corporation <http://www.hygienic.com/english/dipped_tubing_technical_specs.html> (last accessed May 14, 2003)(Tab E); see also, Natural Rubber Latex Tubing Products Specifications, Kent Elastomer Products, Inc. (1999) (Tab F) and Surgical Tubing Specifications, Reef Scuba Accessories <http://reefscuba.com/surgical_tubing_specs.htm>(last accessed on May 14, 2003) (Tab G). Johnson, however, does not teach or suggest varying the hardness of its rubber material or using any material softer than typical surgical rubber tubing to improve the seal or achieve any other advantage in the disclosed mask. Instead, Johnson teaches increasing diameter of the void within the rubber tubing as means to increase resiliency of the seal, disclosing that "[s]electing a length of rubber [tubing] having a relatively large hole results in a

more resiliently accommodating seal.” Johnson, col. 2, lines 53-55. Resiliency, however, is not the same as durometer. Thus, Johnson fails to motivate one of ordinary skill in the art to modify its seal to obtain the seal having the material that has a durometer value of less than about ten on a Shore OOO scale recited in claim 19.

Johnson’s failure to provide the requisite suggestion or motivation to modify the hardness of Johnson’s rubber tubing to arrive at the invention recited in claim 19 is not surprising, however, given the objectives of this reference. In particular, Johnson discloses a face mask that is configured to accommodate differing facial contours among divers and has a seal incorporating pressure compensation to ensure sealing of the mask interior underwater. Johnson’s neoprene layer is approximately one eighth of an inch thick, which, along with the interior rubber tubing, requires a relatively large degree of tightening of a resilient strap about the diver’s head to elastically deform the neoprene layer and the rubber tubing to create a seal. Because the Johnson mask is used for underwater activities, where the integrity of the seal is extremely important, the user’s tolerance for discomfort is relatively high.

In contrast, Applicants’ masks and associated seals allow for comfortable delivery of a breathable gas to a user. Both the softness of a gel seal according to the invention and the design of devices according to the invention which invite minimal contact between the user’s epidermal areas and the device, combine to create a comfortable and reliable seal about the user’s nares. See Specification, page 3, lines 5-8. See also, Specification, page 7, lines 15-21. Applicants disclose that the outer layer of the seal should be thin to avoid stiffening of the seal. See Specification, page 16, lines 13-14. Moreover, Applicants’ seal is configured to seal against external skin proximate at least one naris at a base of a nose of a user. See Specification, page 4, lines 3-4. This delicate area of the user’s face requires minimal contact and pressure to avoid irritation and patient discomfort. See Specification, page 3, lines 4-5.

Additionally, it appears that the knowledge of one skilled in the art would not motivate modifying Johnson to obtain the seal recited in claim 19. In fact, International Patent Application Publication Serial Number WO 97/09090 (“Barnett”), cited in the previous Office Action dated January 4, 2002, discourages a skilled artisan from using as a seal material a very soft gel material with a durometer value below that of a human fat tissue. As such, the skilled

artisan would not be motivated to modify Johnson to include a material having a durometer value less than about ten on the Shore 000 scale. More specifically, Barnett discloses that the facial seal 18 has a resiliency, as defined by durometer measured on the Shore 00 scale, of about 10 or softer and, most preferably, about 0. See Barnett, page 10, lines 2-6. Barnett reports that such resiliency corresponds substantially to that of human fat tissue. See Barnett, page 10, lines 6-9. It is emphasized, however, that the facial seal must exhibit some measurable recoil memory. See Barnett, page 10, lines 33-34. Barnett teaches that to achieve recoil memory and other properties, the annular member is formed from a gel substance that, while purportedly virtually indistinguishable from human fat tissue when measured on Shore 00 scale, exhibits a resiliency or durometer on the Shore 000 scale of from about 20 to about 45. See Barnett, page 11, lines 5-13 (emphasis added). Barnett specifically contrasts the substance with human fat tissue, which registers a durometer of about 10 on the Shore 000 scale. See Barnett, page 11, lines 13-15.

With respect to the statement on page 3 in the Office Action that “Barnett teaches that the seal as a whole should not identically mimic human fat tissue,” not the seal material itself, Applicants respectfully point out that Barnett takes care to explain that the durometer of facial seal 18 corresponds to the resultant durometers of the annular member 27 and its ... protective covering (whose durometer is essentially negligible because of the thinness and pliability of the covering). See Barnett, col. 5, lines 26-30 (emphasis added). Thus, Barnett’s teachings are applicable to the seal material.

More specifically, Barnett states, at page 10, lines 21-33:

[A]ny respiratory mask facial seal possessing structural characteristics essentially identical to fat would be impractical from a usage standpoint. That is, if a facial seal were fabricated from a material structurally indistinguishable from human fat tissue in terms of resiliency, it may tend to sag into an amorphous shape under the influence of gravity and thus would not effectively conform to the contours of a user’s face even if headstrap tension was quite high. It will be appreciated, therefore, that a properly designed facial seal must substantially but not identically mimic human fat tissue from a structural, particularly resiliency, perspective.

Barnett, thus, teaches a skilled artisan not to use soft material of less than about 20 on the Shore 000 scale in order to maintain some resiliency of the seal, at least twice that disclosed and claimed by Applicants. Johnson makes clear that resiliency of its seal depends from the

resiliency of the rubber tubing. See Johnson, col. 2, lines 53-62. Therefore, in view of Barnett's teachings, one of ordinary skill in the art would be discouraged from modifying the hardness of Johnson's tubing to have a durometer value of less than about ten on a Shore OOO scale, because it "would be impractical...." from a structural, particularly a resiliency, perspective.

In view of the remarks set forth above, Applicants respectfully submit that independent claim 19 is novel and non-obvious over Johnson. Accordingly, reconsideration and withdrawal of the rejection of pending claim 19 under 35 U.S.C. § 103(a) as unpatentable over Johnson is respectfully requested. Consequently, Applicants further request reconsideration and withdrawal of the rejection of pending claims 20-29 under 35 U.S.C. § 103(a) because each of the claims depends from allowable base claim 19.

Information Disclosure Statements

As previously mentioned in the Amendment and Response filed on April 1, 2002, as well as in the Response filed on September 26, 2002, Applicants believe the Examiner intended to indicate his consideration of the references listed on page 3 of 5 of the Form PTO-1449 mailed to Patent Office on October 20, 1999 (Tab H). Accordingly, Applicants respectfully request clarification by returning a copy of the Form PTO-1449 with all of the boxes corresponding to all of the references on page 3 of 5 initialed. Additionally, Applicants respectfully request that the Examiner return a copy of the Form PTO-1449 mailed to the Patent Office on January 24, 2000 (Tab I), with all of the boxes corresponding to all of the references listed on the form initialed. A copy of each of the Form PTO-1449s is enclosed, for the Examiner's convenience.

As mentioned before, because these documents were earlier filed in a timely manner, Applicants respectfully submit that no fee is due for their consideration. However, in the event a fee is due for their consideration, authorization is given for charging deposit account 20-0531 for that fee. If other action is required for these references to be considered, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

CONCLUSION

Applicants respectfully submit that, in light of the foregoing Response, claims 19-29 are in condition for allowance and request the application proceed to issue. If, in the Examiner's


opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,

Date: May 19, 2003

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